REMARKS

Claims 3-5, 7-8 and 13-15 are pending in the application. In the Office communication dated September 10, 2002, the Examiner states that support for the amendments to claims 3, 7, 8, and 13 was not provided in the Reply under 37 C.F.R. § 1.111 filed on July 17, 2002.

Claim 3

In the Reply dated July 17, 2002, claim 3 was amended as follows:

> 3. (Four Times Amended) A nucleic acid assay process according to claim 13, wherein [the] said mutated or polymorphic target DNA which is the same as said labeled standard DNA and which is present in said sample DNA is quantitated by evaluating the degree of exchange of the complementary strands between said sample DNA and said labeled standard DNA at the selected excessiveness of said sample DNA, wherein said exchange occurs at a higher frequency when [the] said mutated or polymorphic target DNA is the same as the labeled standard DNA, and said label intensity is reduced.

Thus, the only amendment to claim 3 was the replacement of "the" to "said mutated or polymorphic." Support for mutated or polymorphic is found in claim 13 (see line 8 of claim 13 reproduced below), and in the specification, such as on page 2, line 4, page 6,

line 24, page 7, line 13, etc. No new matter was inserted into this claim by way of this amendment.

Claim 7

In the Reply dated July 17, 2002, claim 7 was amended as follows:

> 7. (Three Times Amended) A nucleic acid assay process according to claim 13, wherein the labeled standard DNA is [the one] prepared by [gene] amplification using a primer having introduced therein a region capable of binding to a solid support.

Thus, claim 7 was amended to merely correct idiomatic language caused by translation of the original application into English. No new matter was inserted into this claim.

Claim 8

In the Reply dated July 17, 2002, claim 8 was amended as follows:

> 8. (Three Times Amended) A nucleic acid assay process according to claim 13, wherein the labeled standard DNA is [the one] prepared by chemical synthesis.

Again, claim 8 was amended to merely correct idiomatic language caused by translation of the original application into English. No new matter was inserted into this claim.

Claim 13

In the Reply dated July 17, 2002, claim 13 was amended as follows:

13. (Four Times Amended) A nucleic acid assay process for identifying and/or quantifying a mutation or polymorphism in a double stranded sample DNA prepared by amplification of a particular region of an analyte nucleic acid which is present in a specimen, comprising the steps of:

providing labeled standard DNA having a nucleotide sequence the same as a mutated or polymorphic target DNA of interest, wherein said labeled standard DNA comprises a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand;

amplifying said particular region of said analyte nucleic acid which is present in said specimen to prepare said double stranded sample DNA[,] for competitive hybridization, wherein said sample DNA comprises both [wild-type and] mutated or polymorphic target DNA and wild-type DNA in an amplifiable amount;

selecting a detection limit for said mutated or polymorphic target DNA, wherein when the detection limit for the target DNA present in said sample DNA is A/B, the excessiveness of said sample DNA is at least B/A, and wherein A/B is the fractional equivalent of the percentage of said mutated or polymorphic target DNA content in the sample DNA and A is at least 3.6×10^{-6} μg;

adding an excessive amount in μg of said sample DNA to said labeled standard DNA, to allow competitive hybridization to take place between said mutated or polymorphic target DNA and labeled standard DNA under conditions which allow for hybridization of at least some of said labeled standard DNA and under conditions wherein non-target sample DNA does not hybridize with said labeled standard DNA, wherein the excessiveness of said sample DNA added to said labeled standard DNA in the

competitive hybridization is calculated as the value of B/A [selected in accordance with the pre-selected detection limit],

detecting the hybridized labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support; and

evaluating the degree of exchange that occurred during competitive hybridization of the complementary strands between said sample DNA and said labeled standard DNA.

In line 15 a comma was deleted and in line 16 a comma was added to improve the claim grammatically. In line 17, the term "wild-type" was deleted and in line 18, the term "wild-type DNA" was inserted. The insertion of wild-type DNA in line 18 is supported by the original recitation thereof in line 17. This portion of the claim was restructured merely to improve the grammar of the claim.

In line 24 and again in lines 29-30, the phrase "said mutated or polymorphic" is inserted. Again, support for this phrase is found in line 8 of claim 13 and in the specification, such as on page 2, line 4, page 6, line 24, page 7, line 13, etc.

Claim 13 was amended in lines 25-26 to recite that the value of A is at least 3.6×10^{-6} μg. As originally presented in the Reply filed on February 6, 2002, this figure represents the weight in one molecule of the mammalian genome. One of ordinary skill in

the art would easily calculate this figure as the weight of one molecule of the mammalian genome, and thusly it does not represent new matter.

The phrase "in μg" was added to line 27. Support for the unit of μg is found on page 14, lines 24-25 of the specification.

In lines 36-38, the recitation of "selected in accordance with the pre-selected detection limit" is replaced with "calculated as the value of B/A." Support for the excessiveness of the sample DNA which is B/A is found on page 19, line 19.

No new matter was inserted into claim 13 by way of the above amendments.

Summary

Applicant respectfully submits that the present invention is in a condition for allowance. Favorable action and early allowance of the claims are respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at 703/205-8000 in the Washington Metropolitan Area.

If necessary, the Commissioner is hereby authorized in this,

concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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